K073605

COOLRAIL LINEAR PEN 510(k) SUMMARY

MAR 11 2008

General Information

Classification	Class II
Trade Name	Coolrail linear pen
Manufacturer	AtriCure, Inc 6033 Schumacher Park Dr West Chester, OH 45069
Contact	Alison M. Grimaldi Clinical & Regulatory Engineer II

Indications for Use

The Coolrail™ Linear Pen (Coolrail Pen) is a sterile, single use electosurgery device intended to ablate cardiac tissue during cardiac surgery using radiofrequency energy.

Predicate Devices

The predicate devices for the Coolrail Linear Pen are the AtriCure Isolator Transpolar Pen (K050459), the Medtronic Cardioblate Monopolar Pen (K013392), and the Boston Scientific Flex 4 Ablation Probe (K003978).

Device Description

The Coolrail Linear Pen is a sterile, single use, electrosurgery device to be used in conjunction with an electrosurgical generator for the delivery of radiofrequency current.

Materials

All materials used in the manufacture of the Coolrail Linear Pen are suitable for this use and have been used in numerous previously cleared products. Testing was conducted in accordance with ISO 10993-1 to ensure appropriate biocompatibility of all materials.

Testing

Appropriate product testing was conducted to evaluate conformance to product specification and substantial equivalence to predicate devices.

Summary of Substantial Equivalence

The Coolrail Linear Pen is equivalent to the predicate products. The indications for use, basic overall funcation, and materials used are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 11 2008

Atricure, Inc.
c/o Mr. Mark Job
Director, Quality and Regulatory Systems
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, MN 55313

Re: K073605
Atricure Coolrail Linear Pen
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II (two)
Product Code: OCL
Dated: December 20, 2007
Received: December 21, 2007

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) _____

Device Name: Coolrail Linear Pen

Indications for Use:

The Coolrail™ Linear Pen is a sterile, single use electosurgery device intended to ablate cardiac tissue during cardiac surgery using radiofrequency energy.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CRF 801 Subpart D) (21 CRF 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K073605